You have written to David Schutz of my staff on 2017-07-18 asking about your abilities under an existing LVE to export for uses and in amounts not approved in that LVE. You described your situation as follows: the Agency recently approved an LVE for a material YOUR COMPANY makes, production volume and uses were limited and you were told to include a PPE requirement in the Safety Data Sheet (SDS). You note that if you had not filed for low volume exemption it would have been permissible to use the export-only exemption from Section 5 notice submission to sell any amount of material and for any use abroad.

You requested that we discuss whether and under what circumstances YOUR COMPANY could sell the material as a [redacted] abroad, whether the material could be exported for incorporation into a [redacted] formulation which would be applied to ARTICLES and the status of those ARTICLES if then exported to the US, whether formulated [redacted] containing the material could be imported to the US, whether a ARTICLE containing the [redacted] could be imported to the US, and whether imported LVE material would count against YOUR COMPANY's quantity limit.

The LVE regulations at 40CFR 723.50 (e)(1)(viii) require that the submitter identify the uses intended for the material, and at 40 CFR 723.50 (j) that the intended uses not be changed without submission of a notice which the Agency will review. There is no exception in the language of the regulations for uses intended to be undertaken outside the US. Obviously, the Agency has no jurisdiction over outside-of-US users who may make use of the LVE material in ways we have not reviewed and approved, but we do have jurisdiction over the US maker and the intent with which the US maker sells the material. This means that you may not sell your material with the intention that it be a [redacted] for [redacted] even if it is formulated outside the US and intended for sale outside the US.

It's not our intention to substitute our judgment for that of the competent regulatory authority in another country, and we expect that, if we receive a modification request from you for this material which seeks permission to sell it outside the US for a use not approved here, we will approve the request if it is submitted along with evidence that you or an intending importer to the other jurisdiction had submitted notice for that use of the material to the competent authority in that country.

Your next question was whether the material could be exported for incorporation into a [redacted] formulation which would be applied to ARTICLES, and if it could whether those [redacted] ARTICLES could be exported to the United States. The discussion above about [redacted] is applicable to whether it could be exported for that purpose. The import questions are different, though. An ARTICLE which had been [redacted] with [redacted] in which the LVE substance had been formulated could be imported by any person other than YOUR COMPANY because the computer would be considered to be an article. For a substance which is incorporated into an article and which will be imported as a part of the article, an importer which holds an LVE on the material is subject to all of the requirements to which it agreed as a condition of receiving

the LVE under 40 CFR 723.50. These requirements include the annual quantity restriction and the customer notification requirements at 40 CFR 723.50 (k). Under 40 CFR 720.22 (b)(1), any importer other than the LVE holder has no requirement for a PMN, nor has it any obligation under the agreements made in the course of obtaining the LVE.

A [redacted] in which the [redacted] had been incorporated would itself also be an article, however in use the [redacted] would fail the 3-part article test (As defined at 40 CFR 720.3(c), an "article" means "...a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article...") because for the [redacted], the end use/commercial purpose is separate from the article and it is intended for release during use, thus it is not exempt.

The [redacted] which included the LVE substance in the formulation could not be imported into the United States unless a section 5 notice (LVE modification if filed by YOUR COMPANY or an LVE or PMN if filed by another intending importer) which allowed that import was filed and successfully reviewed. In this case the LVE material would have been formulated into a product, outside the US, in which its chemical identity does not change. Your question was the status of the LVE material in the formulation is if it is reimported into the US. There are two situations here: import by the LVE holder, and import by any other person.

An importer is considered under the TSCA to be itself manufacturing the material [15 USC 2602(7): 'The term "manufacture" means to import into the customs territory of the United States (as defined in general headnote 2 of the Tariff Schedules of the United States), produce, or manufacture.'] For import of the substance which is incorporated into a formulation and which will be imported as a part of the formulation, a reimporter which has itself exported the material on which it holds an LVE is subject to all of the requirements to which it agreed as a condition of receiving the LVE under 40 CFR 723.50. These requirements include the annual quantity restriction and the customer notification requirements at 40 CFR 723.50 (k). . If you sell any material made pursuant to an LVE domestically, all of that material made and sold counts as part of your year's total. Counter-intuitively, the LVE holder, if it is a reimporter, and even though it has recorded the material against its limit at the time of manufacture, must count the imported material a second time against its quantitative limit.

Because import is equivalent to manufacture in the statute, an importer which is not the original LVE holder for the material must also file an LVE or a PMN to enable it to bring the material into the US for distribution.

Please feel free to contact Dave Schutz, of my staff, if you have questions about this matter. He can be reached on 202 564 9262.